This Response addresses each of the Examiner's rejections and objection. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

With regard to the rejection under 35 U.S.C. §101, the Examiner alleges that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

It is observed that claims 20-27 and 35-48 are drawn to isolated haemopoietin receptors, collectively referred to in the specification as "NR6". The amino acid sequences defining NR6 are set forth in SEQ ID NOs: 13, 15, 17, 19 25 and 29, which are encoded by nucleotide sequences as set forth in SEQ ID NOs: 12, 16, 18, 20, 24 and 28, respectively.

Applicants respectfully submit that the specification asserts specific and substantial utilities of the claimed receptor. In support of the utilities of the claimed receptor, Applicants have provided herewith a Declaration by Dr. Douglas J. Hilton under 37 C.F.R. §1.132 (**Exhibit A**).

In the first instance, Applicants submit that the specification discloses that the lack of NR6 (the claimed receptor) is lethal during embryonic development or immediately after birth. Thus, as asserted at page 32, lines 8-10 of the instant specification, the claimed nucleotides and polypeptides can be used in diagnostic assays for testing individuals to determine the genetic composition of their NR6 genes.

In the Final Action, the Examiner argues that the specification has not asserted that aberrant expression of NR6 is the cause of any disorder, human or mouse, outside of the laboratory. Thus, the Examiner contends that those skilled in the art would not know how to use the claimed sequences to diagnose any particular disorder.

In response, Applicants respectfully submit that an asserted utility can be based on discoveries from research conducted in laboratories, including *in vitro* studies, as long as there is a reasonable correlation between the *in vitro* results and the asserted utility. *See*, *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), which held that, in general, a reasonable correlation between the evidence and the asserted utility is sufficient. *See* also MPEP 2107.03 I.

Applicants respectfully submit that, based on the lethal effects of knocking-out the NR6 gene in mouse and the homologies that the NR6 gene shares with other haemopoietin receptor genes, it certainly can be reasonably extrapolated, that the aberrant expression of the NR6 gene or an expression of a mutant NR6 protein would have a detrimental effect in a developing animal or individual.

Furthermore, Applicants respectfully submit that it is the recognition of the present invention that NR6 is a member of the hemopoietin receptor family. Other important and well-characterized members of this family include receptors for IL-2, IL-3, IL-5, G-CSF, GM-CSF, EPO and many others. Consequently, as all members of this family are involved in regulation of cell proliferation and differentiation, it is apparent that the claimed NR receptor would be involved in similar activities.

Applicants further respectfully direct the Examiner's attention to the Hilton Declaration, which provides evidentiary support for the asserted utility. As stated in paragraph 5 of the Hilton Declaration, it has been shown that a decrease in NR6 results in reduced blood cell production, and it is expected that an increase in NR6 will result in an increase in blood cell production. As further explained in the Hilton Declaration at paragraphs 6-7, given that NR6 has been shown to be involved in haemopoiesis by virtue of the fact that lack of NR6 results in a reduction in the number of blood cells, NR6 provides a further diagnostic target, alone or in

combination with other cytokine receptors, to assess the level of disfunction or lack thereof in the haemopoietin system of a subject.

Accordingly, it is respectfully submitted that the claimed receptor molecules are supported by a specific utility which has been asserted in the specification. As such, withdrawal of the rejection under 35 U.S.C. §101 is respectfully requested.

Claims 20-27 and 35-48 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, the Examiner contends that, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, one skilled in the art would know how to use the claimed invention so that it would operate as intended without undue experimentation. Additionally, the Examiner states that, should Applicants establish a specific and substantial utility for the claimed polypeptides, Applicants have not provided sufficient guidance as to how to make and use the polypeptides which are not 100% identical to the polypeptides of SEQ ID NO: 13, 15, 17, 19, 25 or 29, but which still retain a desired property of the polypeptides of SEQ ID NO: 13, 15, 17, 19, 25 or 29.

Applicants respectfully submit that, as the claimed invention is supported by a specific and substantial asserted utility, as discussed above, one skilled in the art would know how to use the claimed invention without undue experimentation. Applicants further submit that it is within the ken of those skilled in the art to make polypeptides which are not 100% identical to the polypeptides of SEQ ID NO: 13, 15, 17, 19, 25 or 29, but which still retain a desired property of the polypeptides of SEQ ID NO: 13, 15, 17, 19, 25 or 29. As such, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 20-27 and 35-41 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Examiner points out that claim 20, clause (i) and claim 35 require that amino acid sequences have a certain degree of "similarity", yet claim 20, clause (ii) requires that nucleotide sequences have a certain degree of sequence "identity". The Examiner suggests that the term "% identity" be used for both amino acid and nucleotide sequences.

In an effort to favorably advance the prosecution of the present case, Applicants have amended claims 20 and 35 to use the term "identity" in place of "similarity."

Furthermore, the Examiner contends that claims 20, 39 and 41 are indefinite for reciting the phrase "high stringency conditions" without defining the conditions. Claim 41 is also alleged to be indefinite for not including the temperature of the wash conditions.

Applicants respectfully submit that the term "high stringency conditions" is routinely used and well understood by those skilled in the art. However, Applicants have amended claim 41 to include the temperature to be used for washing.

Claim 39 contains the term [SEQ ID NO:1]. The Examiner contends that the use of the brackets is confusing because the brackets imply that the sequence identifier is to be deleted through amendment.

Claim 39 has been amended to replace the brackets with parentheses.

In view of the foregoing, the rejection under 35 U.S.C. §112, second paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

Claims 20, 22-27, 37, 39 and 43 are objected to because the sequence identifiers in the claims require a space, e.g., "SEQ ID NO:13" should be "SEQ ID NO: 13".

Applicants have amended claims 20, 22-27, 37, 39 and 43 to insert a space in the sequence identifiers where appropriate. Withdrawal of the objection is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**"

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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Enclosures:

- Version with markings to show changes made;
- Declaration by Dr. Hilton under 37 C.F.R.§1.132.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend the claims as follows:

20. (Twice Amended) An isolated haemopoietin receptor comprising:

(iv) an amino acid sequence having at least about 90% [similarity] identity to the amino acid sequence set forth in any one of SEQ ID NO:_13, 15, 17, 19, 25 and 29;

(v) an amino acid sequence encoded by a nucleotide sequence having at least about 85% identity to the nucleotide sequence set forth in any one of SEQ ID NO:_12, 14, 16, 18, 24 and 28; or

(vi) an amino acid sequence encoded by a nucleotide sequence which hybridizes under high stringency conditions to the nucleotide sequence set forth in any one of SEQ ID NO:_12, 14, 16, 18, 24 and 28;

wherein said receptor further comprises the amino acid motif:

Trp Ser Xaa Trp Ser (SEQ ID NO:_1)

wherein Xaa is any amino acid.

22. (Twice Amended) The isolated haemopoietin receptor according to claim 21 comprising the amino acid sequence set forth in SEQ ID NO:_13.

23. (Twice Amended) The isolated haemopoietin receptor according to claim 21 comprising the amino acid sequence set forth in SEQ ID NO:_15.

24. (Twice Amended) The isolated haemopoietin receptor according to claim 21 comprising the amino acid sequence set forth in SEQ ID NO:_17.

25. (Twice Amended) The isolated haemopoietin receptor according to claim 21 comprising the amino acid sequence set forth in SEQ ID NO:_19.

26. (Twice Amended) The isolated haemopoietin receptor according to claim 21 comprising the amino acid sequence set forth in SEQ ID NO:_25.

27. (Twice Amended) The isolated haemopoietin receptor according to claim 21 comprising the amino acid sequence set forth in SEQ ID NO:_29.

35. (Amended) An isolated haemopoietin receptor comprising an amino acid sequence having at least about 90% [similarity] identity to the amino acid sequence set forth in any one of SEQ ID NO: 13, 15, 17, 19, 25 and 29, wherein said receptor further comprises the amino acid motif:

Trp Ser Xaa Trp Ser (SEQ ID NO:_1)

wherein Xaa is any amino acid.

37. (Amended) An isolated haemopoietin receptor comprising an amino acid sequence encoded by a nucleotide sequence having at least about 85% identity to the nucleotide sequence set forth in any one of SEQ ID NO:_12, 14, 16, 18, 24 and 28, wherein said receptor further comprises the amino acid motif:

Trp Ser Xaa Trp Ser (SEQ ID NO:_1)

wherein Xaa is any amino acid.

39. (Amended) An isolated haemopoietin receptor comprising an amino acid sequence encoded by a nucleotide sequence which hybridises under high stringency conditions to the nucleotide sequence set forth in any one of SEQ ID NO:_12, 14, 16, 18, 24 and 28, wherein said receptor further comprises the amino acid motif:

Trp Ser Xaa Trp Ser [[] (SEQ ID NO:_1)[]]

wherein Xaa is any amino acid.

41. (Amended) An isolated haemopoietin receptor according to claim 39 wherein said high stringency conditions comprise from at least about 31% v/v to at least about 50% v/v formamide [and from at least about 0.01M to at least about 0.15M salt] for hybridisation, and from at least about 0.01M to at least about 0.15M salt at about 42°C for washing [conditions].

43. (Amended) An isolated haemopoietin receptor comprising the amino acid sequence set forth in SEQ ID NO:_13.

44. (Amended) An isolated haemopoietin receptor comprising the amino acid sequence set forth in SEQ ID NO:_15.

45. (Amended) An isolated haemopoietin receptor comprising the amino acid sequence set forth in SEQ ID NO:_17.

46. (Amended) An isolated haemopoietin receptor comprising the amino acid sequence set forth in SEQ ID NO:_19.

47. (Amended) An isolated haemopoietin receptor comprising the amino acid sequence set forth in SEQ ID NO:_25.

48. (Amended) An isolated haemopoietin receptor comprising the amino acid sequence set forth in SEQ ID NO:_29.